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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,386	12/12/2001	Kevin P. Baker	GNE.2830P1C55	9794

35489 7590 12/02/2004

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EXAMINER	
LANDSMAN, ROBERT S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/015,386	BAKER ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-35,38-40 and 44-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *28-35 and 38-40* is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/10/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Formal Matters

A. The Amendment dated 11/10/04 has been entered into the record.

B. Claims 28-47 were pending. Claims 36, 37 and 41-43 have been canceled and new claims 48-57 have been added. Therefore, claims 28-35, 38-40 and 44-57 are pending and are the subject of this Office Acion.

C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Priority

A. Applicants argue that the present invention relies on the skin vascular permeability assay, the glucose/FFA assay and the chondrocyte re-differentiation assay for patentable utility. However, as addressed below in the rejection under 35 USC 101, only the chondrocyte re-differentiation assay is a suitable utility. Therefore, Applicants receive priority to PCT/US00/04343, filed February 18, 2000.

3. Information Disclosure Statement

A. The Information Disclosure Statement dated 11/10/04 has been entered into the record. All references have been considered.

4. Specification

A. All objections to the specification have been withdrawn in view of Applicants' amendments. However, regarding 09/380,137, it is noted that the Preliminary Amendment dated 8/29/02, as referred to by Applicants, cannot be found in the record.

5. Claim Objections

A. The objection to claims 28-35 and 38-40 and 44-47 has been withdrawn in view of Applicants' amendments to the claims.

6. Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

A. Claims 44-57 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a specific, substantial and credible asserted utility or a well established utility. These claims are directed to polynucleotides encoding polypeptides at least 80% identical to SEQ ID NO:227 and which can induce an inflammatory response or can stimulate the uptake of glucose or FFA in adipocytes. However, the invention encompassed by these claims has no apparent or disclosed patentable utility. This rejection is consistent with the current utility guidelines, published 1/5/01, 66 FR 1092. The instant application has provided a description of an isolated protein. However, the instant application does not disclose a specific and substantial biological role of this protein or its significance.

Applicants have not disclosed what type of "inflammatory response" is being induced, or why this would be a specific and substantial utility. It appears that Applicants are relying on the vascular permeability test as a test for the ability of a compound to induce an inflammatory response. However, this is only a toxicity test and does not provide a real-world, readily available use.

Furthermore, it is not clear from the specification whether the claimed polypeptide is involved in the uptake of glucose ***or*** FFA. Regardless, this asserted utility is credible but not substantial or specific. Such assays can be performed with any polypeptide; thus, the asserted utility is not specific. Furthermore, the specification discloses no details about the assays or the results. Applicant implies that stimulation or inhibition of glucose and/or FFA uptake supports a useful function for the PRO1325 polypeptide. However, patentable utility of stimulation or inhibition of glucose and/or FFA uptake claimed PRO1325 polypeptide is not substantial, because one skilled in the art would not readily use the PRO1325 sequences for stimulation or inhibition of glucose and/or FFA uptake in a real world sense as the protein is not specific to one tissue and is not associated with any disease or disorder. In addition, evidence of stimulation or inhibition of glucose and/or FFA uptake in a tissue is not tantamount to a showing of a role for the polypeptide of the present invention. It is not clear if a positive test for the polypeptide of the present Invention is correlated with a specific change in physiology, for example, or with a disease state. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

Furthermore, since the nucleic acids of the invention are not supported by a specific and substantial asserted utility or a well established utility, the vector, host cell, polypeptide and method for producing the claimed polypeptide also lack utility.

7. Claim Rejections - 35 USC § 112, first paragraph - enablement

A. Claims 48-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to adequately teach how to use the instant invention. Specifically, since the claimed invention is not supported by a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

B. The rejection of claims 28-35, 38-40 and 44-47 under 35 USC 112, first paragraph, has been withdrawn in view of the fact that Applicants have met all the requirements for Deposit.

C. The rejection of claims 28-35, 38-40 and 44-47 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' amendments to the claims to recite a functional limitation.

D. No rejection is being made over claims 46 and 47 even though it does not recite that the host cell is "isolated." When read in light of the specification, these claims do not read on gene therapy. As defined in the specification "host cells are transfected or transformed with expression or cloning vectors described herein for PRO production *and cultured in conventional nutrient media* modified as appropriate for inducing promoters, selecting transformants, or amplifying the genes encoding the desired sequences" (emphasis added). The fact that these cells are cultured in conventional media demonstrates that these host cells are not transgenic. **However, it is recommend by the Examiner that the term "isolated" be added to the claims (i.e. "isolated host cell") in order to further clarify that the cells are, in fact, not transgenic**.

8. Claim Rejections - 35 USC § 112, first paragraph – written description

A. The rejection of claims 28-35, 38-40 and 44-47 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' amendments to the claims to recite a functional limitation.

9. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of claims 28-35, 38-40 and 44-47 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants' amendments to the claims to remove reference to the "extracellular domain."

10. Claim Rejections - 35 USC § 102

A. The rejection of all claims under 35 USC 102 has been withdrawn in view of Applicants' cancellation of claims 41-43 and the removal of "extracellular domain" from the claims.

11. Conclusion

A. Claims 28-35 and 38-40 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 9 AM-6 PM (eastern); alt F 9 AM-6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert Landsman
Primary Examiner
Art Unit 1647

ROBERT LANDSMAN
PATENT EXAMINER